RATIONALE FOR THE DEVELOPMENT OF ONTARIO AIR STANDARDS FOR ETHYLENE DICHLORIDE

CONSULTATION DRAFT

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Executive Summary

The Ontario Ministry of the Environment has identified the need to develop and/or update air quality standards for priority contaminants. The Ministry's Three Year Plan for Standards Setting which was released in October 1996, identified candidate substances for the development of air standards for the next several years. Ethylene dichloride (1,2-dichloroethane) was identified as priority for review based on recent toxicological information published since the existing standard was developed in 1985.

Ethylene dichloride is a colourless liquid with an odour which is typical of chlorinated solvents. In Canada, ethylene dichloride is used primarily as an intermediate in the synthesis of vinyl chloride. It is also used in the production of anti-knock fluids for export. It is rarely detected in atmospheric samples in Ontario where the annual average levels are near or below the analytical detection limit of 0.1 $\mu g/m^3$ (microgram ethylene dichloride per cubic metre of air).

There is sufficient evidence to consider ethylene dichloride as an animal carcinogen with liver, lung and mammary glands as the principal target organs. There is also evidence that ethylene dichloride can cause mutations to genetic material in a number of mammalian and non-mammalian cell types. In human epidemiological studies, occupational exposures have been reported to affect the central nervous system and the liver. However, these studies were unable to clearly demonstrate whether ethylene dichloride is a human carcinogen. Based on the evidence of carcinogenicity in animals and the ability of ethylene dichloride to cause mutations in genetic material, a number of regulatory agencies classify ethylene dichloride as a probable human carcinogen.

The current standards for ethylene dichloride in Ontario are as follows: the interim half-hour Point of impingement standard is 1200 $\mu g/m^3$, while the 24-hour average Ambient Air Quality Criterion is 400 $\mu g/m^3$. While both values are based on human health considerations, neither is based on carcinogenicity as an end-point. As a result of new toxicological information, these Ontario standards, developed in 1985, are now considered out of date.

In developing air quality standards for Ontario, the Ministry of the Environment is reviewing and considering air quality guidelines and standards used by leading agencies world-wide. A number of agencies have developed life-time cancer risk estimates for ethylene dichloride. Of these, the estimate developed by the United States Environmental Protection Agency of 0.4 $\mu g/m^3$ at a risk level of one in a hundred thousand is judged to have the most appropriate rationale.

Based on an assessment of ambient air quality guidelines used in other jurisdictions; the toxicity of this compound; the levels of ethylene dichloride measured in Ontario; and modelled ground level concentrations from recent applications for Certificates of Approval, the Ministry is proposing to establish:

- an annual average Ambient Air Quality Criterion for ethylene dichloride of 0.4 $\mu g/m^3$;

- a 24-hour average Ambient Air Quality Criterion for ethylene dichloride of 2 µg/m^3 to replace the existing 24-hour AAQC of 400 µg/m^3; and

- a point of impingement guideline for ethylene dichloride of 6 µg/m^3 to replace the existing interim point of impingement standard of 1200 µg/m^3. The point of impingement guideline will be used to review and assess applications for Certificates of Approval involving emissions of ethylene dichloride from new or modified sources.

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1.0 Introduction

Ontario's primary approach to regulating air emissions is based on achieving and maintaining air quality which is protective of human health and the environment. The *Environmental Protection Act* requires all stationary sources which emit or have the potential to emit a contaminant to obtain a Certificate of Approval which outlines the conditions under which the facility can operate.

Compliance with air quality standards and guidelines is one of the criteria used to issue Certificates of Approval. Sources or potential sources of a contaminant are required to control emissions to ensure that the concentration of a contaminant specified by the standard is not exceeded at any point off their property. Dispersion modelling which incorporates detailed engineering calculations is used to relate emission rates from a source to resulting ambient concentrations of a particular contaminant.

The Ministry of the Environment uses a combination of regulatory standards, ambient air quality criteria (AAQCs) and point of impingement (POI) guidelines in reviewing Certificates of Approval (MOEE, 1994a). Point of impingement standards are established under Regulation 346 and can be used directly as enforcement tools as the regulation specifies that a source cannot emit a contaminant at a level which would result in a standard being exceeded at its maximal point of impingement off its property (Section 5(3)). All sources are required to comply with Regulation 346 POI standards unless they are specifically exempted in regulation. As POI standards specified under Regulation 346 apply to all sources, socio-economic issues need to be taken into consideration in their development to ensure that the standards are technically feasible and there is a balance between the benefits and costs of improved ambient air quality.

In addition to POI standards established under Regulation 346, the Ministry also has a larger number of ambient air quality criteria and point of impingement guidelines which are derived from AAQCs. These are used by the Ministry to assess general air quality and the *potential* for causing an adverse effect (MOEE 1994). Like POI standards specified in Regulation 346, point of impingement guidelines are also used in Certificates of Approval to approve new and modified emission sources. Once incorporated into a legal instrument like a Certificate of Approval, point of impingement guidelines are legally binding, however unlike Regulation 346 POI standards, they do not automatically apply to existing sources at the time they are promulgated. AAQCs are normally set at a level not expected to cause adverse human health or environmental effects based on continuous exposure. As such, socio-economic factors such as technical feasibility and costs are not explicitly considered when establishing such limits.

Generally, point of impingement standards and guidelines which employ half-hour averaging times are set such that compliance with the standard or guideline will ensure that the Ambient Air Quality Criterion which is based on longer term averaging periods (e.g. 24-hours) will be met. In certain cases where the effect can occur over short-term exposures, like odours, the 24-hour Ambient Air Quality Criterion and the half-hour point of impingement standard may have the same value.

The Ontario Ministry of the Environment has identified the need to develop and/or update air guidelines/standards for priority toxic contaminants. The Ministry's Standards Plan which was released in October 1996, identified candidate substances for the development of air standards for the next several years. Ethylene dichloride was identified as priority for review based recent toxicological information published since the existing standard was developed in 1985. This document provides the rationale for recommending a revised AAQC and POI standard for ethylene dichloride..

2.0 Review and Evaluation

2.1 General Information

Ethylene dichloride (1,2-dichloroethane) is a colourless liquid which is slightly soluble in water. Ethylene dichloride has an odour described as "typical of chlorinated hydrocarbons" (ACGIH, 1991). An odour threshold of 88 ppm (approx. 350 mg/m^3) has been reported (ACGIH, 1991). The Chemical Abstracts Service (CAS) identification number is 107-06-2, the Registry of Toxic Effects of Chemical Substances (RTECS) number is KI0525000 and the United Nations Hazardous Material number is 1184.

High exposures in the workplace have been reported to cause mortalities in a few cases. Liver and kidney damage, and pulmonary edema were reported in these cases. Nausea, vomiting and dizziness (attributed to central nervous system effects), and liver and blood abnormalities have also been reported from exposures of between 10 and 50 ppm (ACGIH, 1991).

The International Agency for Research on Cancer (IARC, 1987) classified ethylene dichloride as possibly carcinogenic to humans, based on insufficient evidence of carcinogenicity in epidemiological data and sufficient evidence of carcinogenicity in animals. According to the USEPA (USEPA, 1997) and the State of California (California Department of Health Services, 1985), inhalation exposure of Wistar, Sprague-Dawley rats and Swiss mice did not result in increased tumour incidence, but exposure by gavage resulted in the induction of several tumour types in rats and mice. In addition, lung papillomas were observed in mice after topical application. The USEPA (1996) describes ethylene dichloride as a probable human carcinogen.

2.2 Sources and Levels

Ethylene dichloride is used as an intermediate in the manufacture of vinyl chloride, in the manufacture of anti-knock fluids in leaded gasoline and as a degreaser (CEPA, 1994; ACGIH, 1991). It is currently produced in Canada by one company in Fort Saskatchewan, Alberta (CEPA, 1994). Results from the 1995 National Pollutant Release Inventory show two sources in Ontario. The 1995 Lambton Industrial Society (LIS-Sarnia area) report shows a third source. The total release to air in Ontario reported for all three sources in 1995 was 0.035 tonnes.

Ethylene dichloride is rarely detected at monitoring sites in Ontario, and annual average levels are near or below the analytical detection limit of 0.1 µg/m^3 (micrograms per cubic metre of air). Ethylene dichloride has been measured above the detection limit in only 6% of 389 samples from several cities in Ontario between 1989 and 1991 (CEPA, 1994). Samples measured in the Sarnia area by the LIS showed its maximum 24-hour average level (#samples = 30) to be at 0.30 µg/m^3 during the 1996 calendar year. The annual average at the LIS Sarnia site for the period 1992-96 was in the range 0.06-0.25 µg/m^3 . Measurements at a downtown Windsor site over the period 1988-92 showed the annual average in the range 0.04-0.17 µg/m^3.

Ethylene dichloride has been detected in ambient air samples from 12 Canadian cities in 6 provinces at a frequency of greater than 60%. Between 1988 and 1990, concentrations in 1,412 samples ranged from non-detectable (below 0.1 µg/m^3) to a maximum of 2.78 µg/m^3 in Edmonton, Alberta. Mean concentrations at these sites ranged between 0.07 and 0.28 µg/m^3. Concentrations as high as 16, 38 and 45-113 ppb (64 to 452 µg/m^3) have been recorded outside production and users sites (industrial) in the United States (HSDB, 1996).

Maximum ground level concentrations (half-hour average) of ethylene dichloride, associated with Certificate of Approval applications over the past several years, were determined for various types of facilities in Ontario. Five industrial facilities were identified as sources of more than a trace amount of ethylene dichloride. The median, maximum and minimum values were 6.5, 600 and 0.154 µg/m^3, respectively. The certificates of approval covered a variety of emission sources including laboratory fume hoods, curing ovens and groundwater remediation systems.

2.3 Review of Existing Air Quality Regulations

Agency-specific summaries of information concerning air quality guidelines for ethylene dichloride are presented in the Appendix of this report. A brief summary is presented in Table 1.

The current Ontario guidelines for ethylene dichloride are human health-based. The half-hour point of impingement limit is 1,200 μg/m^3, while the 24-hour Ambient Air Quality Criterion is 400 μg/m^3 (MOEE, 1994b). Using conditions of 1 atmosphere pressure and 10°C, 1.0 μg/m^3 = 0.235 ppb. Various agencies use conversion factors based on temperatures between 0°C and 25°C. Conversion of units carried out by different agencies may vary slightly, depending which temperature they have chosen to employ.

2.4 Strategic Options for the Management of Ethylene Dichloride under the Canadian Environmental Protection Act

Ethylene dichloride has been assessed as toxic under the *Canadian Environmental Protection Act* (CEPA). As such, Environment Canada must develop management strategies to minimize the environmental release of the substance during all phases of its life cycle. The Strategic Options Process (SOP) for ethylene dichloride is focussed on reducing releases during the production of the substance. Currently (1998) there is only one ethylene dichloride producer in Canada

(Alberta). It is likely that any strategic options that apply to Ontario sources will be generic in nature.

3.0 Development of an Ambient Air Quality Criterion for Ontario

3.1 Regulatory Approaches for Ethylene dichloride

The development of ambient air standards and acceptable exposure limits for long-term exposure to ethylene dichloride is based on two approaches: those based on the avoidance of injury to the central nervous system and the liver, and those based on the avoidance of cancer in the liver (based on inference from animal studies). The two approaches will be examined separately.

Table 1. Summary of Existing Air Quality Guidelines[1] for Ethylene Dichloride

Agency, Date[2]	Guideline(s)		Comments
USEPA (IRIS) 1991	no ambient air exposure limits are available		
	0.4 μg/m^3 0.04 μg/m^3	(lifetime exposure) (lifetime exposure)	$1*10^{-5}$ additional cancer risk $1*10^{-6}$ additional cancer risk both are based on unit risk of $2.6*10^{-5}$ tumours/(μg/m^3)
California 1992	0.5 μg/m^3 0.05 μg/m^3	(lifetime exposure) (lifetime exposure)	$1*10^{-5}$ additional cancer risk $1*10^{-6}$ additional cancer risk both based on unit risk of $2*10^{-5}$ tumours/(μg/m^3);
	95.0 μg/m^3 400 μg/m^3	(current inhalation reference exposure level) (proposed inhalation reference exposure level - 1997)	to be used for evaluation of non-cancer risks: alimentary system, nervous system
WHO 1987	700 μg/m^3	(24-hour average)	based on a non-cancer endpoint
Netherlands 1987	1 μg/m^3 200000 μg/m^3 7.5 μg/m^3	(target value) (maximum acceptable concentration) (maximum emission concentration)	All values are based on a risk assessment in Dutch
Sweden[3] 1993	400 μg/m^3	(long-term average)	based on an endpoint of cancer and a cancer-threshold approach to risk assessment
New York 1990	950 μg/m^3	(1-hour average)	1-hour average based on occupational exposure limits;
	0.039 μg/m^3	(annual average)	$1*10^{-6}$ additional cancer risk based on a unit risk of $2.5*10^{-5}$ tumours/(µg/m^3)
Massachusetts 1990	11.01 µg/m^3	(24-hour ceiling limit)	24-hour average based on occupational exposure limits;
	0.04 µg/m^3	(allowable ambient limit)	$1*10^{-6}$ additional cancer risk based on a unit risk of $2.6*10^{-5}$ tumours/(µg/m^3)
Ontario (current) 1985	1,200 μg/m^3 400 μg/m^3	(1/2-hour point of impingement limit) (24-hour limit)	POI limit based on health AAQC limit based on health

1. Guidelines in this table can refer to: guidelines, risk-specific concentrations based on cancer potencies, and non-cancer-based reference concentrations.
2. Date here refers to when the health-based guideline background report or original legislative initiative was issued. Sources were the respective agency documents.
3. Proposed by the Swedish Institute of Environmental Medicine.

3.1.1 Regulatory Approaches for Ethylene Dichloride Based on Carcinogenicity Endpoint

Ethylene dichloride is considered an animal carcinogen by IARC (1987), the USEPA (1996), the State of California (California Department of Health Services, 1985), the Commonwealth of Massachusetts (Commonwealth of Massachusetts, 1990) and by Environment Canada and Health Canada under the Canadian Environmental Protection Act (CEPA, 1994). The USEPA and the State of California relied on a study by the U.S. National Cancer Institute (NCI, 1978) in which ethylene dichloride in corn oil was administered by gavage to groups of male and female Osborne-Mendel rats and B6C3F1 mice. Dosages were 47 and 95 mg/kg/day for rats, 97 and 195 mg/kg/day for male mice and 149 and 299 mg/kg/day for female mice. The oral carcinogenic potency was then converted to an inhalation unit risk. California used 5 different models for estimating risk and chose a unit risk of $2.0*10^{-5}$. The USEPA reported a unit risk of $2.6*10^{-5}$. New York State (NYDEC, 1991) and the Commonwealth of Massachusetts (1990) chose to use the unit risk calculated by the USEPA. Sweden also considers ethylene dichloride to be potentially carcinogenic; however, they used a safety factor approach, dividing the lowest observed dose in which cancer was observed in animal studies by a safety factor of 5000 (Victorin, 1993).

3.1.2 Regulatory Approaches for Ethylene dichloride Based on a Non-Carcinogenic Endpoint

The ACGIH (1991) and NIOSH (1988, as cited in NYDEC, 1991) developed occupational standards to prevent narcosis and injury to the liver. In some jurisdictions (Commonwealth of Massachusetts, 1990; NYDEC, 1991), a short-term limit was based on extrapolation from this occupational standard. In California a non-cancer Reference Exposure Level for long-term exposure was also developed by extrapolating from an occupational standard (CAPCOA, 1990). (As noted in Table 1, California is proposing to revise the Reference Exposure Level up to 400 $\mu g/m^3$.)

Studies of occupational exposure to ethylene dichloride show that adverse effects on the CNS and the liver may result, but the limited data do not allow a definitive conclusion regarding a lowest-observed-adverse-effect-level (WHO, 1987). A no-observed-effect-level in laboratory animals of 400 mg/m^3 and a lowest-observed-adverse-effect-level (LOAEL) of 700 mg/m^3 has been demonstrated. Applying a protection factor of 1000 to the LOAEL, WHO (1987) recommended a guideline of 700 $\mu g/m^3$.

3.2 Recommendations for an Ambient Air Quality Criterion for Ethylene Dichloride

Recommendations for new or revised Ontario Ambient Air Quality Criteria (AAQC) and Point of Impingement (POI) standards are based upon a weight-of-evidence evaluation of available information. Information for guidelines, based on cancer and non-cancer endpoints, from various agencies were reviewed, allowing the final guideline recommendation to be made by MOEE staff.

The World Health Organization (1987) has developed a health-based guideline of 700 µg/m^3, and California (CAPCOA, 1993) and Massachusetts (1990) have developed non-carcinogenic-based criteria of 95 µg/m^3 and 11.01 µg/m^3, respectively. These guidelines were derived for occupational limits and were modified by adjusting the occupational exposure to environmental exposure, and by applying various uncertainty factors. The Dutch Government (Netherlands MHSPE, 1994) has set a target value of 1 µg/m^3 for ethylene dichloride. Target values point towards the goals that pollution reduction measures should eventually reach. Sweden (Victorin, 1993) has also stated its intention to phase out chlorinated solvents, primarily through European cooperation. The target value approach is clearly not consistent with the desire for an ambient air quality guideline based on direct consideration of human and environmental health information.

Several agencies have developed cancer risk estimates including USEPA (USEPA, 1996) the States of California CAPCOA, 1993), New York (NYDEC, 1991) and Massachusetts (Commonwealth of Massachusetts, 1990) and Environment Canada and Health Canada under the Canadian Environmental Protection Act (CEPA, 1994). These carcinogenicity-based approaches have received wide public review, including reviews by government, corporate and non-governmental organization scientists and risk assessors. They are strengthened by common reference to information and methodology. Thus, they are reflective of broad consensus on the issue of carcinogenicity-based air quality guidelines.

Sweden also considers ethylene dichloride to be a possible carcinogen. However, in developing a value, Sweden has used a safety factor approach. Information contained in the Swedish documents indicates that this approach is used for compounds which appear to be carcinogenic but do not appear to be mutagenic. The reasoning behind this approach is that compounds which are not mutagenic but appear carcinogenic are likely to function through a threshold mechanism. For these compounds, exposures at levels below the threshold, would not be expected to result in an increased level of cancer risk. The CEPA evaluation of ethylene dichloride states that there is sufficient evidence to conclude that ethylene dichloride is consistently mutagenic. In light of this evidence it would appear that the Swedish safety factor approach would not be an appropriate basis upon which to establish guidelines for ethylene dichloride.

There is sufficient consensus among different jurisdictions to support the development of ambient air quality criteria based on the carcinogenicity of ethylene dichloride. Of the cancer risk estimates reviewed the value developed by the USEPA is considered to have the most appropriate rationale. The unit risk estimate developed by the USEPA corresponds to an ambient air exposure levels of 0.4 and 0.04 μg/m^3 at additional lifetime carcinogenic risk levels of 10^{-5} and 10^{-6} respectively. The Ministry of the Environment recommends that an air quality guideline of 0.4 μg/m^3 which corresponds to a lifetime risk estimate of 1/100,000 be used as the basis for developing an annual average Ambient Air Quality Criterion for ethylene dichloride in Ontario.

Half-hour point of impingement limits used for reviewing applications for Certificates of Approval are normally derived such that the AAQCs based on longer averaging times are not exceeded. The relationship between short-term maxima and long-term average concentrations is empirically based, and is derived from an examination of monitoring data for which both short-term and long-

term measurements can be obtained. To convert from an annual average (0.4 µg/m^3) to a 24-hour maximum, a standard conversion factor of 5 is typically used. Similarly, to convert from a 24-hour average to an half-hour maximum, a standard conversion factor of 3 is typically used although depending on the critical end-point being considered other factors may be employed (MOEE 1994c). Using these conversion factors, the recommended 24-hour AAQC for ethylene dichloride is 2 µg/m^3 and the half-hour point of impingement guideline is 6 µg/m^3 (Table 2).

Table 2: Recommended AAQCs and POI Guideline for Ethylene Dichloride

AAQC	Annual Average	0.4 µg/m^3
AAQC	24-hour Average	2.0 µg/m^3
POI Guideline	half-hour Average	6.0 µg/m^3

At this time the Ministry is recommending a point of impingement guideline for ethylene dichloride which will be used to assess applications for certificates of approval involving emissions of ethylene dichloride. Because of the limited number of sources of ethylene dichloride in Ontario, the development of a point of impingement standard under Regulation 346 is not warranted at this time.

While an AAQC of 2 µg/m^3 (24-hour average) is based on the prevention of adverse health effects in the human population, the potential effect of ethylene dichloride on other terrestrial biota including plants, soil microbes and herbivores was also examined, and found lacking in information. The effects on plant life are unknown. However, if future studies indicate that the proposed AAQC is not protective of other terrestrial biota in Ontario, then the basis on which the AAQC is established may need to be reviewed.

4.0 Status of Stakeholder Consultations

In January 1997, the Ministry initiated limited stakeholder consultation on the initial suite of 14 proposed air standards developed under the Standards Plan. The purpose of these consultations was to seek comments from Ontario sources and other stakeholders on the standards proposed During the course of these consultations, no comments or concerns were identified with respect to the proposed standards for ethylene dichloride.

Based on an analysis of past Certificates of Approval, the Ministry recognizes that a small number of sources in Ontario may have predicted ground level concentrations which exceed the proposed point of impingement guideline for ethylene dichloride. Where necessary, the Ministry will follow-up with sources to identify how ground level concentrations based on current emission levels compare to the proposed point of impingement guideline.

5.0 Recommendations:

Based on an assessment of ambient air quality guidelines used in other jurisdictions; the toxicity of this compound; the levels of ethylene dichloride measured in Ontario; modelled ground level concentrations from recent applications for Certificates of Approval, the Ministry is proposing to establish:

- an annual average Ambient Air Quality Criterion for ethylene dichloride of 0.4 $\mu g/m^3$.
- a 24-hour average Ambient Air Quality Criterion for ethylene dichloride of 2 $\mu g/m^3$ to replace the existing 24-hour AAQC of 400 $\mu g/m^3$.
- a point of impingement guideline for ethylene dichloride of 6 $\mu g/m^3$ to replace the existing interim point of impingement standard of 1,200 $\mu g/m^3$. The point of impingement guideline will be used to review and assess applications for Certificates of Approval involving emissions of ethylene dichloride from new or modified sources.

6.0 References:

ACGIH, 1991. Documentation Of The Threshold Limit Values for Substances in Workroom Air (6th ed.). American Conference of Governmental Industrial Hygienists Inc., Cincinnati, OH.

California Department of Health Services, 1985. Report on Ethylene Dichloride to the Scientific Review Panel: Health Effects of Ethylene Dichloride. The Epidemiological Studies Section, Department of Health Services, State of California, Berkeley, CA.

CAPCOA, 1993. Air Toxics "Hot Spots" Program. Revised 1992 Risk Assessment Guidelines. Toxics Committee of the California Air Pollution Control Officers Association.

CEPA, 1994. Canadian Environmental Protection Act, Priority Substances List Assessment Report for 1,2-dichloroethane.

Commonwealth of Massachusetts, 1990. The Chemical Health Effects Assessment Methodology and the Method to Derive Allowable Ambient Limits, Volumes I and II. Commonwealth of Massachusetts, Department of Environmental Protection, Boston, MA.

Commonwealth of Massachusetts, 1995. Massachusetts Threshold Effects Exposure Limits (TEL) and Allowable Ambient Limits (AAL) for Ambient Air. Commonwealth of Massachusetts Executive Office of Environmental Affairs, Department of Environmental Protection, Boston, MA.

Heppel et al., 1946. The toxicology of 1,2-dichloroethane (ethylene dichloride). V. The effect of daily inhalations. J. Indust. Hyg.Toxicol. 28:113-120.

Hofmann, H.T., et al., 1971. Zur Inhalationstoxizität von 1,1- und 1,2-Dichloräthan (On the inhalation toxicity of 1,1- and 1,2-dichloroethane). Archiv. für Toxikologie, 27:248-265.

HSDB (Hazardous Substances Database), 1996. CISTI, Ottawa, Ont.

IARC, 1987. IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Humans. Genetic and Related Effects: An Updating of Selected IARC Monographs from Volumes 1 to 42. Supplement 6. International Agency for Research on Cancer, Lyon, France. 697+ p.

Lewis D.C. and G.V. Alexeeff, 1989. Quantitative Risk Assessment of Non-cancer Health Effects for Acute Exposure to Air Pollutants. In: Proceedings of the Air and Waste Management Association 82nd Annual Meeting. June 1989, Vol. 89-91. 4 p.

McCloskey, E., 1985. Recommended Ambient Air Guideline for Ethylene Dichloride. Ontario Ministry of Labour, Toronto Ont.

McConnell, E.E., 1995. Historical review of the rodent bioassay and future directions. Reg. Toxicol. Pharmacol., 21:38-43.

MOEE, 1994a. Windsor Air Quality Study: Health Effects Assessment. Appendices 1-24. Ontario Ministry of the Environment and Energy, Toronto, Ont.

MOEE, 1994b. Summary of Point of Impingement Standards, Ambient Air Quality Criteria (AAQC) and Approvals Screening Levels (ASL). Standards Development Branch, Ontario Ministry of the Environment and Energy, Toronto, Ont.

MOEE, 1994c. Rationale for the Development of Soil, Drinking Water and Air Quality Criteria for Lead. Ministry of Environment and Energy, Toronto, Ont.

NCI (National Cancer Institute), 1978. Bioassay of 1,2-dichloroethane for possible carcinogenicity. NCI Carcinogenesis Technical Report Series No. 55, DHEW Publication No (NIH) 78-1361. US. Government Printing Office, Washington, D.C.

NeR Staff Office, 1992. Netherlands Emission Regulations - Air. Netherlands Emission Regulations Staff Office, Bilthoven, The Netherlands. 81 p. + Appendices.

Netherlands MHSPE, 1994. Environmental Quality Objectives in The Netherlands. A review of environmental quality objectives and their policy framework in The Netherlands. Risk Assessment and Environmental Quality Division, Ministry of Housing, Spatial Planning and the Environment, The Hague, The Netherlands. 465 p.

NYDEC, 1991. New York State Air Guideline -1. Guidelines for the Control of Toxic Ambient Air Contaminants. Draft. New York State Department of Environmental Conservation, Albany, N.Y. 20 p. + Appendices.

Spencer et al., 1951. Vapour toxicity of ethylene dichloride determined by experiments on laboratory animals. Arch. Indust. Hyg. Occup. Med. 4:482-493.

USEPA (United States Environmental Protection Agency), 1985. Health assessment document for 1,2-dichlorethane (ethylene dichloride). National Technical Information Service, Springfield, VA.

USEPA, 1996. Integrated Risk Information System (IRIS) Database. U.S. Environmental Protection Agency, Washington, D.C.

Victorin, K., 1993. Health effects of urban air pollutants: guideline values and conditions in Sweden. Chemosphere, 27:1691-1706.

WHO, 1987. Air Quality Guidelines for Europe. WHO Regional Publications, European Series No. 23. World Health Organization, Regional Office for Europe, Copenhagen, Denmark. 426p.

7.0 Appendix: Agency-Specific Reviews of Air Quality Guidelines

7.1 Agency-Specific Summary: Federal Government of the United States

1. Name of Chemical: ethylene dichloride

2. Agency: U.S. Environmental Protection Agency

3. Guideline Value(s):
No ambient air exposure limits are currently promulgated. There is no Reference Concentration (RfC) for chronic inhalation exposure in the IRIS database (USEPA, 1995). There are, however, quantitative estimates of carcinogenic risk from inhalation exposure. The inhalation unit risk is $2.6*10^{-5}$ tumours/($\mu g/m^3$). Using a linearized multistage extra risk model extrapolation procedure, this represents an additional risk of 1 in 100,000 to 1 in 1,000,000 per 0.4 $\mu g/m^3$ or 0.04 $\mu g/m^3$ of lifetime exposure respectively.

4. Application:
IRIS was developed as a source for consistent risk information on chemicals for use in decision-making and regulatory activities. However, values derived and presented in IRIS do not represent guidelines or standards in and of themselves. IRIS also contains a summary of current American government regulatory actions under various legislative mandates.

5. Documentation Available:
USEPA, 1996. Integrated Risk Information System (IRIS) Database. U.S. Environmental Protection Agency, Washington, DC.

Key Reference(s):
NCI (National Cancer Institute), 1978. Bioassay of 1,2-Dichloroethane for Possible Carcinogenicity. NCI Carcinogenesis Technical Report Series No. 55. DHEW Publ. No. (NIH) 78-1361, Washington, DC, as cited in USEPA, 1995.

USEPA, 1995. Integrated Risk Information System (IRIS) Database. U.S. Environmental Protection Agency, Washington, DC.

6. Peer Review Process and Public Consultation:
Peer-reviewed scientific research data, analyses and evaluations from various sources, including a variety of public and government agencies from around the world and the published scientific literature, were employed in the development of these values. Both the general assessment methodologies and the chemical-specific information found in IRIS undergo extensive scientific and policy reviews, within both the USEPA and other science-based U.S. regulatory agencies. Information in IRIS is put forward for use after the results of the public review and comments on draft documents/information have been addressed.

7. Status of Guideline:
No guideline exists. The risk estimate discussed is for respiratory exposure from air only.

8. Key Risk Assessment Considerations:
The USEPA considers ethylene dichloride (1,2-dichloroethane) to be a probable human carcinogen, based on no evidence from human studies and sufficient evidence of carcinogenicity in animal models. According to the USEPA, inhalation exposure of Wistar and Sprague-Dawley rats and Swiss mice did not result in increased tumour incidence (Spencer *et al*., 1951; Maltoni *et al*., 1980). An elevation in lung adenomas that was not statistically significant was seen in A/st mice treated i.p. with 1,2-dichloroethane in tricaprylin (Theiss *et al*., 1977). ICR/Ha Swiss mice treated topically had a significant increase in benign lung papillomas, but not skin carcinomas (van Duuren *et al*., 1979).

Ethylene dichloride (1,2-dichloroethane) in corn oil was administered by gavage to groups of 50 each male and female Osborne-Mendel rats and B6C3F1 mice. Treatment was for 78 weeks followed by an additional observation period of 12-13 weeks for mice or 32 weeks for low-dose rats. TWA dosages were 47 and 95 mg/kg/day for rats, 97 and 195 mg/kg/day for male mice and 149 and 299 mg/kg/day for female mice. All high-dose male rats died after 23 weeks of observation; the last high-dose female died after 15 weeks. Male rats had significantly increased incidence of forestomach squamous-cell carcinomas and circulatory system hemangiosarcomas. Female rats and mice were observed to have significant increases in mammary adenocarcinoma incidence. Mice of both sexes developed alveolar/bronchiolar adenomas, females developed endometrial stromal polyps and sarcomas, and males developed hepatocellular carcinomas (NCI, 1978). Based on the induction of several tumour types in rats and mice treated by gavage and lung papillomas in mice after topical application, the USEPA considered ethylene dichloride to be an animal carcinogen.

A inhalation unit risk was calculated from oral data, assuming 100% absorption and metabolism at the low dose. Equivalent human dose was calculated using an assumed 70-kg human weight and the reported terminal rat weight of 0.5 kg. Metabolism of 1,2-dichloroethane after oral exposure is dose-dependent. Metabolism was estimated to be <50% saturation at the dose equal to the TWA for rats, but near saturation for the high-dose mice in the NCI (1978) bioassay. Because of the high mortality rate in the high-dose rats, a time-to-event analysis was used to quantitate the risk estimate. It was assumed that rats with hemangiosarcomas were killed by the tumours. The 95% upper bound of the risk was calculated to be $9.1*10^{-2}$ tumours per (mg/kg)/day, using 90 weeks to approximate the lifetime risk and a linearized multistage procedure which accounted for time-to-death. Adequate numbers of animals were treated and observed for the majority of their expected lifespan. The incidence of hemangiosarcoma was significantly elevated in the treated animals and was dose-related. According to the USEPA, an oral slope factor of $6.2*10^{-2}$ (mg/kg)/day, calculated from data on hepatocellular carcinomas in male mice (NCI, 1978), is supportive of their risk estimate.

To calculate a unit risk for inhalation, the average inhalation rate of 20 m^3 per day and a body weight of 70 kg were applied. Assuming a concentration of 1 $\mu g/m^3$ of ethylene dichloride in the

air, the dose, assuming 100% absorption, would be 20 µg/70 kg = 0.00028 mg/kg. The tumour rate of $9.1*10^{-2}$ tumours/(mg/kg)*0.00028 mg/kg = $2.548*10^{-5}$ tumours. Thus the inhalation unit risk would be $2.6*10^{-5}$ tumours/(µg/m^3).

9. Key Risk Management Considerations:
None, since no guideline for ambient air exists.

10. Multimedia Considerations of Guidelines:
None are reported

11. Other Relevant Factors:
According to the USEPA, ethylene dichloride is mutagenic for Salmonella in assays wherein excessive evaporation was prevented; exogenous metabolism by mammalian systems enhanced the response (Nestmann *et al*., 1980; Barber *et al*., 1981; Rannug *et al*., 1978). Both somatic cell mutations and sex-linked recessives were induced in Drosophila (Nylander *et al*., 1979; Shakarnis, 1969, 1970; King *et al*., 1979). Metabolites of 1,2-dichloroethane have been shown to form adducts with DNA after *in vitro* or *in vivo* exposures.

According to the USEPA, in the NCI (1978) study, adequate numbers of animals were treated and observed for the majority of their expected lifespan.

7.2 Agency-Specific Summary: State of California

1. Name of Chemical: ethylene dichloride

2. Agency: State of California (Office of Environmental Health Hazard)

3. Guideline Value(s):
The State of California states that the unit risk of $2.0*10^{-5}$ tumours/($\mu g/m^3$) is to be used for evaluation of cancer risks (CAPCOA, 1993). At risk levels of 10^{-5} and 10^{-6} this corresponds to concentrations of ethylene dichloride in air of 0.5 $\mu g/m^3$ and 0.05 $\mu g/m^3$ respectively. The Reference Exposure of 95 $\mu g/m^3$ is given for non-cancer risk assessment (CAPCOA, 1993).

4. Application:
"The intent of the Committee in developing the guideline was to provide risk assessment procedures for use in the Air Toxics 'Hot Spots' Program." (CAPCOA, 1993). This program is based on a California State law: the Air Toxics 'Hot Spots' Information and Assessment Act of 1987 (Health and Safety Code Section 44360 *et seq*.). The act specifies how local Air Pollution Control Districts determine which facilities in their areas will prepare health risk assessments, how such health risk assessments should be prepared and how the results are to be prioritized. These guidelines were prepared to provide consistent risk assessment methods and report presentation to enable: 1) comparisons between facilities, 2) expeditious review of risk assessments by reviewing agencies, and 3) minimal revisions and resubmittals of risk assessments. The various health-based exposure levels developed for and employed in this program should not be employed outside the framework of the program. That is to say, the State of California does not consider them to be general, independent, legally enforceable air quality guidelines or limit values at this time.

5. Documentation Available:
CAPCOA, 1993. CAPCOA Air Toxics "Hot Spots" Program. Revised 1992 Risk Assessment Guidelines. Toxics Committee of the California Air Pollution Control Officers Association.

Key Reference(s):
California Department of Health Services, 1985. Report on Ethylene Dichloride to the Scientific Review Panel: Health Effects of Ethylene Dichloride. The Epidemiological Studies Section, Department of Health Services, State of California, Berkeley, CA.

NCI (National Cancer Institute), 1978. Bioassay of 1,2-dichloroethane for possible carcinogenicity. NCI Carcinogenesis Technical Report Series No. 55, DHEW Publication No (NIH) 78-1361. U.S. Government Printing Office, Washington, DC, as cited in California Department of Health Services, 1985.

6. Peer Review Process and Public Consultation:
Cancer potency slope factors and acute and chronic reference levels were prepared by the California Office of Environmental Health Hazard Assessment (OEHHA), and these, as well as

the exposure and health assessments, have undergone public review and comment prior to finalization. Peer-reviewed scientific research data were employed in the development of these values. Under the CAPCOA risk assessment process, each assessment is site-specific, and public notice to all exposed individuals is required when screening determines that a significant health risk is associated with emissions from a facility. Public input was obtained in identifying and ranking areas and facilities for risk assessment screening and, according to the documentation, additional input is expected as the process moves forward.

7. Status of Guideline:
Current, but updates are possible, with new California risk assessment guidelines being considered in the California Senate.

8. Key Risk Assessment Considerations:
California (CAPCOA, 1993) calculated a non-cancer reference exposure level by dividing the threshold limit value of 40 mg/m^3 by 420 (4.2 to extrapolate from a 40-hour work week to a 168-hour full week times 10 to extrapolate from healthy workers to sensitive ones, and times 10 since adverse effects are often seen at the TLVs).

According to the State of California (California Department of Health Services, 1985), inhalation studies using animal models are negative for carcinogenicity (Maltoni *et al.*, 1980) but oral administration demonstrates carcinogenicity in both sexes of two animal species (NCI, 1978). The State of California performed a risk assessment using hemangiosarcomas of the male rat and hepatocellular carcinomas of the male mouse and derived from risk estimates using 5 models for exposure to ethylene dichloride in air. The five models were: a one-hit model, a multistage model, a multistage model (time corrected), a probit model, and a gamma multi-hit model. They estimated excess risk over background and recommended the use of a lifetime excess risk value of between 53 and 88 per million for community exposure to 1 part per billion, equivalent to $2.2*10^{-5}$ tumours/($\mu g/m^3$). This recommendation was based on the results of the multistage model (time corrected) for rat hemangiosarcomas (California Department of Health Services, 1985).

9. Key Risk Management Considerations:
The exposure guidelines were prepared for both non-cancer- and cancer-based endpoints. The cancer-based value is to be used in a screening risk assessment to determine the maximum offsite cancer risk for the exposed human population. The process is not readily comparable to the air quality guideline approach to non-carcinogens. The non-cancer guidelines are based on the most sensitive adverse health effect reported in the scientific literature and are designed to protect the most sensitive individuals in the population.

There are options for addressing the possible economic impacts of controlling ethylene dichloride emissions. It appears that the options are under local control and are based on local risk and socio-economic analyses, as well as public workshops and hearings. The enforcement mechanism is via operating permits. The process is therefore primarily directed towards site-specific evaluations and development of further regulatory tools, rather than being enforceable levels in and of themselves.

10. Multimedia Considerations of Guidelines:
In the exposure modeling process, non-inhalation pathways should be considered for a number of substances (specified in Table III-5 in CAPCOA, 1993). Ethylene dichloride is not one of the substances that require non-inhalation modeling. In the California EPA exposure and health assessments it was acknowledged that exposure pathways other than air (e.g., water and food) were possible but that, due the lack of quantitative information and the predominance of airborne exposure, other exposure pathways were not considered in the development of the guideline.

11. Other Relevant Factors:
No information

7.3 Agency-Specific Summary: World Health Organization

1. Name of Chemical: ethylene dichloride

2. Agency: World Health Organization

3. Guideline Value(s):
The value of 700 $\mu g/m^3$ for continuous exposure (averaging time 24 hours) is recommended as a guideline value. This guideline relates only to accidental release episodes or specific indoor pollution problems.

4. Application:
"The guidelines are intended to provide background information and guidance to governments in making risk management decisions, particularly in setting standards. It should be strongly emphasized that the guideline values are not to be regarded as standards in themselves." (WHO, 1987, pg. xiii).

5. Documentation Available:
WHO, 1987. Air Quality Guidelines for Europe. WHO Regional Publications, European Series No. 23. World Health Organization, Regional Office for Europe, Copenhagen, Denmark. 426 p.

Key references:
Heppel et al., 1946. The toxicology of 1,2-dichloroethane (ethylene dichloride). V. The effect of daily inhalations. Journal of Industrial Hygiene and Toxicology, 28:113-120, as cited in WHO, 1987.

Hofmann, H.T. et al., 1971. Zur Inhalationstoxizität von 1,1- und 1,2-Dichloräthan (On the inhalation toxicity of 1,1-, and 1,2-dichloroethane). Archiv. für Toxikologie, 27:248-265, as cited in WHO, 1987.

Spencer et al., 1951. Vapour toxicity of ethylene dichloride determined by experiments on laboratory animals. Archives of Industrial Hygiene and Occupational Medicine, 4:482-493 , as cited in WHO, 1987.

6. Peer Review Process and Public Consultation:
Scientific background documents were prepared by experts and submitted to working groups consisting of international experts. After a series of meetings and internal and external reviews by experts and representatives of Member States of the Region, the resultant conclusions and recommendations were presented at a final meeting, where they were adopted by consensus of the representatives. In addition, peer-reviewed scientific research data were employed in the development of these documents.

7. Status of Guideline:
No information

8. Key Risk Assessment Considerations:
According to the WHO (1987), human studies point to effects on the CNS and the liver, but the limited data do not allow a definitive conclusion regarding a lowest-observed-adverse-effect level (LOAEL). In animals, long-term inhalation exposure (>6 months) to ethylene dichloride levels of approximately 700 mg/m^3 and above has been seen to result in histological changes in the liver (Spencer *et al*., 1951; Heppel *et al*., 1946; Hofmann *et al*., 1971). The same animal studies reported no adverse histological changes in the liver and kidneys of guinea pigs and rats at levels of about 400 mg/m^3. In summary, animal data suggest a no-observed-effect-level in laboratory animals of 400 mg/m^3 and a lowest-observed-adverse-effect-level of 700 mg/m^3. A protection factor of 1000 was applied to the LOAEL to calculate a guideline of 700 µg/m^3.

Evidence of carcinogenicity is sufficient in animal studies for the oral route of exposure, but there is no positive evidence from inhalation studies. Because of deficiencies in extrapolating from oral data to inhalation data, available inhalation unit risks from the USEPA were not adopted (WHO, 1987).

9. Key Risk Management Considerations:
Since the recommended guideline value is above current environmental levels and present exposures are not of concern to health, this guideline relates only to accidental release episodes or specific indoor pollution problems.

10. Multimedia Considerations of Guidelines:
Human exposure from air, drinking water and diet was considered in the evaluation, but this did not specifically contribute to the determination of the final guideline value.

11. Other Relevant Factors:
No information

7.4 Agency-Specific Summary: The Netherlands

1. Name of Chemical: ethylene dichloride

2. Agency: Netherlands Ministry of Housing, Spatial Planning and the Environment

3. Guideline Value(s):
The maximum acceptable concentration (MAC) is 200 mg/m^3. The maximum emission concentration (MIC) for airborne effluents from point sources is 7.5 μg/m^3. Ethylene dichloride is listed as a substance black-listed for air. Substances black-listed for air are recommended to be reduced with all available means. The target value is 1 µg/m^3.

4. Application:
Limit values are non-statutory environmental quality objectives that are considered policy guidelines. They should not be exceeded and should be considered as requirements to be met. These effects-oriented guidelines may be used simultaneously with source-oriented emission criteria, although it is the latter that are the primary regulatory mechanism. If effects-oriented guidelines continue to be exceeded, then existing source-oriented emissions criteria will be lowered to bring ambient levels below the effects-oriented guidelines. A maximum acceptable concentration (MAC) is the maximum acceptable concentration of a gas, vapour, or mist of a substance in a workplace.

5. Documentation Available:
Netherlands MHSPE, 1994. Environmental Quality Objectives in The Netherlands. A review of environmental quality objectives and their policy framework in The Netherlands. Risk Assessment and Environmental Quality Division, Ministry of Housing, Spatial Planning and the Environment, The Hague, The Netherlands. 465 p.

NeR Staff Office, 1992. Netherlands Emission Regulations - Air. Netherlands Emission Regulations Staff Office, Bilthoven, The Netherlands. 81 p. + Appendices.

Earlier air criteria documents or more recent integrated criteria documents are available for priority substances such as ethylene dichloride, but only in Dutch.

6. Peer Review Process and Public Consultation:
No specific information on this issue was presented in the available English language documentation.

7. Status of Guideline:
Current

8. Key Risk Assessment Considerations:
No information

9. Key Risk Management Considerations:
National limit values include consideration of environmental, economic and social interests as well as technical options. Specific information on such details was not presented in the available documentation.

10. Multimedia Considerations of Guidelines:
Multimedia exposure was not considered in the development of the current air guideline limits; however, intercompartmental criteria which address this problem are being developed. A specific schedule for revisions based on this process has not been announced, and ethylene dichloride is not on the initial list of chemicals to be considered.

11. Other Relevant Factors:
No information

7.5 Agency-Specific Summary: Swedish Institute of Environmental Medicine

1. Name of Chemical: ethylene dichloride

2. Agency: The values reported below are those recommended by the Swedish Institute of Environmental Medicine. According to Dr. K. Victorin of the Swedish Institute of Environmental Medicine (pers. comm.), no official Swedish air quality guidelines have been promulgated by the Swedish Environmental Protection Agency.

3. Guideline Value(s):
The recommended value from the Institute of Environmental Medicine is a long-term average of 400 $\mu g/m^3$.

4. Application:
Used on an *ad hoc* basis

5. Documentation Available:
Victorin, K., 1993. Health effects of urban air pollutants: guideline values and conditions in Sweden. Chemosphere, 27:1691-1706.

Although documentation in Swedish has been prepared no English language version is available.

6. Peer Review Process and Public Consultation:
No information was available in the documentation.

7. Status of Guideline:
It has no official status but has been used on an *ad hoc* basis by Swedish regulators.

8. Key Risk Assessment Considerations:
Ethylene dichloride (dichloroethane) is assessed along with trichloroethene, tetrachlorothene and methylene chloride as a compound that has an effect on the central nervous system upon inhalation and gives rise to liver damage and tumours in mice and other animal models. According to Victorin (1993), none of these compounds are not clearly genotoxic. The lowest-effect level for tumour induction in animal experiments was divided by a safety factor of 1000 to 5000 to arrive at a low-risk level for humans of about 100 ppb.

9. Key Risk Management Considerations:
This guideline is generally not exceeded in urban air. The Swedish Government (1991) intends to phase out chlorinated solvents, primarily through European cooperation.

10. Multimedia Considerations of Guidelines:
Based on human health considerations for respiration only.

11. Other Relevant Factors:
Dichloroethane is mainly used for the production of other chemicals, especially vinyl chloride, and is thus emitted from such industries.

7.6 Agency-Specific Summary: New York State

1. Name of Chemical: ethylene dichloride

2. Agency: New York State

3. Guideline Value(s):
The recommended 1-hour average is 950 µg/m^3. The recommended annual average is $3.9*10^{-2}$ (0.039) µg/m^3 (moderate) based on a lifetime carcinogenic risk level of 10^{-6}.

4. Application:
". . . they are primarily intended for use in conjunction with the permitting authority and regulatory concerns found in 6NYCRR Parts 200, 201, 212 and 257." (NYDEC, 1991, p. 1). These regulations refer specifically to construction and operation (Certificate to Operate) permits for any sources of air contamination. Rather than being employed as legally enforceable, ambient air quality standards, the guidelines are to be employed to aid in the regulatory decision-making process. This process includes the classification of chemicals into groups of high, moderate and low toxicity. The regulatory screening process considers the toxicity classification and the emission rate potential from a facility. An air emission dispersion model is also specified in the process to guide regulators in their assessment of chemical emissions from sources of interest. Both long-term and short-term effects are considered.

5. Documentation Available:
NYDEC, 1991. New York State Air Guideline -1. Guidelines for the Control of Toxic Ambient Air Contaminants. Draft. New York State Department of Environmental Conservation, Albany, N.Y. 20 p. + Appendices.

6. Peer Review Process and Public Consultation:
The scientific documents prepared by New York State employed peer reviewed data and models, as well as the professional judgements of its scientific staff. There are opportunities for public comment on guidelines and the guideline development process, but specific information on the process for ethylene dichloride was not presented in the available documentation.

7. Status of Guideline:
Current

8. Key Risk Assessment Considerations:
New York State (1991) has classified the toxicity of ethylene dichloride (1,2-dichloroethane) as moderate. Compounds given the designation of moderate are animal oncogens, developmental and reproductive toxicants, genotoxic chemicals and other chemicals posing a health hazard to humans. For compounds in this classification, the short-term guideline was developed by dividing a chosen occupational standard by 4.2. In the case of ethylene dichloride, New York used the occupational standard of 1 ppm (4 mg/m^3) (NIOSH REL-TWA, 1988, as cited in NYDEC,

1991). The annual carcinogenicity-baed guideline of 0.039 $\mu g/m^3$ was based on the USEPA unit risk value of $2.5*10^{-5}$ tumours/($\mu g/m^3$) and a goal of an individual risk of $1*10^{-6.}$

9. Key Risk Management Considerations:
A specific computer model and guidance manual are provided for use of the guidelines in impact screening analyses as employed in the permitting process. The latest version of Appendix B of the New York State Air Guide -1 is dated April 4, 1994.

10. Multimedia Considerations of Guidelines:
Considers human airborne exposure only

11. Other Relevant Factors:
No information

7.7 Agency-Specific Summary: Commonwealth of Massachusetts

1. Name of Chemical: ethylene dichloride

2. Agency: Commonwealth of Massachusetts

3. Guideline Value(s):
A 24-hour ceiling limit is 11.01 $\mu g/m^3$, based on the threshold effects exposure limit (TEL). The allowable ambient limit (AAL) is 0.04 $\mu g/m^3$ for an annual (1 year) averaging time and is based on consideration of carcinogenic effects at a 10^{-6} level of risk.

4. Application:
". . . the Division of Air Quality Control, which is responsible for implementing the Department's air programs, plans to employ the AALs in the permitting, compliance and enforcement components of the Commonwealth's air program in general, and the air toxics program in particular." (Commonwealth of Massachusetts, 1990, Volume 1, pg. ix). The primary goal is to "protect the public health and welfare from any air contaminant causing known or potentially injurious effects." The ambient air levels developed in this process should not be considered legally enforceable air quality standards, since they deal only with health-related matters and contain no consideration of technological, economic or enforcement concerns. Rather, they should be employed as guidelines in the development of subsequent regulatory action which does contain a broad consideration of all relevant concerns.

5. Documentation Available:
Commonwealth of Massachusetts, 1990. The Chemical Health Effects Assessment Methodology and the Method to Derive Allowable Ambient Limits, Volumes I and II. Commonwealth of Massachusetts, Department of Environmental Protection, Boston, MA.

Commonwealth of Massachusetts, 1995. Massachusetts Threshold Effects Exposure Limits (TEL) and Allowable Ambient Limits (AALs) for Ambient Air. Commonwealth of Massachusetts Executive Office of Environmental Affairs, Department of Environmental Protection, Boston, MA.

Key Reference(s):
ACGIH, 1986. Documentation Of The Threshold Limit Values for Substances in Workroom Air (5th ed.). American Conference of Governmental Industrial Hygienists Inc., Cincinnati, OH.

USEPA (United States Environmental Protection Agency), 1985. Health assessment document for 1,2-dichlorethane (ethylene dichloride). National Technical Information Service, Springfield, VA.

6. Peer Review Process and Public Consultation:
Peer-reviewed scientific research data, analyses and evaluations from various sources, including a variety of public and government agencies from around the world and the published scientific

literature, were employed in the development of these values. Specifically, evidence from the International Agency for Research on Cancer (IARC), the American National Toxicology Program (NTP) and the USEPA was employed. As guidelines, the process used and values generated are not subject to the extensive review and consultation that air quality standards would be subjected to, but external peer reviews were carried out, and public input was solicited through at least two public meetings on the Massachusetts methodology and guideline document (D. Manganaro, Massachusetts Department of Environmental Protection, pers. comm.).

7. Status of Guideline:
Current. Although guideline values are periodically updated, revisions to the current value for ethylene dichloride are not under consideration (D. Manganaro, Massachusetts Department of Environmental Protection, pers. comm.).

8. Key Risk Assessment Considerations:
The Commonwealth of Massachusetts (1990) has a method for establishing a limit that assumes the compound has a threshold for adverse effects. In the case of ethylene dichloride, the 1986 ACGIH occupational limit, reported to be 40 mg/m^3 (ACGIH, 1986; reported as 40.45 mg/m^3), was divided by several factors that attempt to extrapolate from a worker health-based limit to a public limit that protects children and other sensitive individuals. The uncertainty factor incorporates judgments about the amount of information about the toxicity of the compound, the differences between body sizes and weights between adult males and children and an assumption about the relative contribution of the compound to the total exposure from air. The total uncertainty factor in the case of ethylene dichloride was 3,674.

The Commonwealth of Massachusetts (1990) reported that they reviewed the risk assessments of the USEPA (1985) and the State of California (1985). They agreed that ethylene dichloride was a probable human carcinogen. They chose to adopt the USEPA risk assessment and adopted the unit risk of $2.6*10^{-5}$ tumours/($\mu g/m^3$). They noted that both the USEPA and the State of California calculated lower carcinogenic risks, based on the inhalation study of Maltoni *et al.*, (1980). They stated that it was preferable to use the unit risk based on oral exposure because it could not be ruled out that the lower apparent potency via inhalation might be due to differences in species sensitivity or to an inadequate conversion of the inhalation exposure to metabolized dose.

9. Key Risk Management Considerations:
The primary objective of the process is the protection of public health. The Massachusetts system uses hazard assessment only and does not use the number of exposed individuals as a criterion for regulatory action. Furthermore, the selection of the AAL is based on the most sensitive effect. The USEPA's cancer unit risk values (USEPA, 1985) and the ACGIH occupational TLV values were adopted for regulation development purposes. For carcinogens, a maximum allowable increase in risk associated with exposure to a chemical was set at one per million (10^{-6}) for a 70-year lifetime.

10. Multimedia Considerations of Guidelines:
A generic allowance was made for contributions from sources other than respiration: "A relative source contribution factor of 20% is also included to account for sources other than air." (Commonwealth of Massachusetts, 1990, pg. viii).

11. Other Relevant Factors:
According to the Commonwealth of Massachusetts (1990), because the carcinogenic potency was based on a gavage study and there is assumed to be no difference between routes of exposure, the potency value cited may be used for other routes of exposure.